



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,131	02/16/2001	Adrian Gilbert	60623-A/JPW/GJG/CSN	5640

7590 07/31/2003  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 10036

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/788,131

Applicant(s)

GILBERT ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-43,50-55 and 61-66 is/are pending in the application.
- 4a) Of the above claim(s) 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-43,50-54 and 61-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1644

### DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application claims the benefit of the filing date of Provisional Application No. 60/183,666, filed February 18, 2000.

Claims 44-49 and 56-60 have been canceled previously.

Claim 2 has been canceled herewith.

Claims 62-66 have been newly added.

Claims 1, 3-43, 50-55 and 61-66 are currently pending.

### *Election/Restrictions*

1. Applicant has traversed the withdrawal of claims 2-22, 25-35, 39, 43, 50-54 and 61 by the Examiner, asserting that the claims are not mutually exclusive of the elected species. Upon further consideration, the aforementioned claims are being rejoined and are examined in the present Office Action. However, it is noted that claim 2 has been canceled and therefore cannot be examined.

Accordingly, claim 55 is withdrawn.

Claims 1, 3-43, 50-54 and 61-66 are the subject of examination in the present Office Action.

### *Response to Arguments*

2. Applicant's arguments with respect to claims 1 and 23-24 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

3. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 36 recites that the pharmaceutical composition is in an aqueous form. However, the claim is dependent upon claim 32, which is dependent upon claim 1. Claim 1 recites that the composition comprises both copolymer-1 and microcrystalline cellulose. Microcrystalline cellulose is a well known in

Art Unit: 1644

the art as a stable and physiologically inert exipient for solid compositions such as tablets, not for liquid formulations. The specification discloses the formulation and use of copolymer-1 in solution at page 10, lines 19-27 and Example 2, for example. However, the specification discloses only the formulation of copolymer-1 into the solution and does not disclose the addition of microcrystalline cellulose to said solution. Accordingly, there is no written description of a solution or liquid form of the pharmaceutical composition comprising both copolymer-1 and microcrystalline cellulose.

4. Claims 19, 61 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "said enteric coating" in line 2. There is no antecedent basis for this limitation in the claim. There is no support for the recitation in base claim 1. Applicant should amend the claim to be dependent upon claim 18, which contains the proper antecedent basis.

Claim 61 is indefinite in the recitation of "protease inhibitor." It is suggested that the claim be amended to recite --protease inhibitor--.

Claim 66 is indefinite in that it is dependent upon a canceled claim. Applicant should amend the claim to be dependent upon claim 65, which contains the proper antecedent basis.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3-43, 50-54 and 62, 63 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-14 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892)

Art Unit: 1644

Specifically, claims 7-11 of the '791 patent are drawn to the use of copolymer-1 for the manufacture of a medicament or pharmaceutical composition for the treatment of multiple sclerosis via ingestion or inhalation (7), wherein the medicament comprises 0.1-1000 mg of copolymer-1 (8), is formulated for oral or nasal administration (9), is administered via inhalation (10), or is enterically coated (11). Claim 7 of the '791 patent is a genus claim which broadly encompasses the presently claimed method of making a copolymer-1 medicament in light of the disclosure of the '981 patent [Instant claims 43 and 64-65]. Claims 12-14 are drawn to a pharmaceutical composition for the treatment of multiple sclerosis via ingestion or inhalation (12), wherein the pharmaceutical composition is in solid, liquid, aerosol or inhalable powder form (13), or is enterically coated (14). Claim 12 of the '791 patent is a genus claim which broadly encompasses the presently claimed pharmaceutical composition in light of the further disclosure of the '791 patent and the disclosure of the '981 patent.

The pharmaceutical composition recited in claim 12 of the '791 patent comprises as an active ingredient a therapeutically effective amount of Copolymer 1 (glatimer acetate). As is evidenced by the disclosure of the '791 patent, the composition is used to treat multiple sclerosis by oral administration of copolymer-1 through ingestion, and that when copolymer-1 is introduced orally it may be in solid form, and it may be mixed with pharmaceutically acceptable carrier. The disclosure of the '791 patent indicates that the use of enteric coatings is well known in the art, including methacrylic acid copolymer (Eudragit L; column 3, lines 27-42 in particular) [Instant claims 18, 20, 29-31]. The '791 patent further discloses that the administration of the composition orally, nasally or bronchially in liquid or solid form with a range of copolymer-1 from 0.1 to 1000 mg (column 2, line 45 to column 3, line 26) [claims 23-28, 32-42, 50-54, 62-63].

The '791 patent does not specifically recite that said carrier is microcrystalline cellulose or admixture with a lubricant.

Microcrystalline cellulose is well known in the art as a stable and physiologically inert excipient. The '981 patent teaches that microcrystalline cellulose is a non-effervescent wicking or disintegration agent for solid compositions such as tablets (column 13, lines 47-59 in particular) and that tablets can be made in unit dosage forms adapted for oral administration (column 4, lines 30-35). The '981 patent teaches that the percentage of active ingredient, and therefore of the carrier in proportion to that active ingredient, in a solid pharmaceutical preparation may be selected according to known principals of pharmacy (column 5, lines 12-14 in particular). The '981 patent teaches that the active ingredient used can vary greatly and is generally provided in an amount between greater than zero and 80% (column 5, lines 34-56 in particular). The '981 patent teaches that a typical range for a disintegrant such as

Art Unit: 1644

microcrystalline cellulose is conventionally as high as 20% but can be increased for rapidly disintegrating dosage forms (column 13, lines 60-67 in particular)[Instant claims 1, 3-8]. The '981 patent also teaches modified starches as a disintegration agent (column 13, lines 47-59 in particular)[Claims 8-14]. The '981 patent further teaches lubricants, including magnesium stearate (column 10, lines 13-51 in particular)[claims 15-17]. Claims 34-35 are included because the use of preservatives in pharmaceutical formulations is well known to enhance the longevity of the formulation in storage.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to manufacture a composition comprising copolymer-1 as recited in claims 7-14 of the '791 patent using the well-known microcrystalline cellulose as an expient and magnesium stearate as a lubricant, optimizing the proportions of active ingredient as taught by the '981 patent. One would have been motivated to combine these teachings because thus formed composition can be used as a medicament.

6. Claims 1, 20, 21, 22, 43 and 64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-14 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892) and U.S. Patent No. 5,965,600 to Sato et al (B on form PTO-892).

The '791 and '981 patents have been discussed supra.

The combined disclosures do not specifically recite film coating of the solid form in combination with the enteric coating.

The '600 patent teaches a medicament in tablet form comprising both an enteric coating and a film coating, which could be polyvinyl alcohol (column 4, lines 39-62 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '600 patent with the combined disclosures of the '791 and '981 patents. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '600 patent that multiple coatings of a tablet including both enteric and film coatings is "customary" in the art.

7. Claims 1 and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 6,214,791 to Arnon et al (on form

Art Unit: 1644

PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892) and U.S. Patent No. 6,162,800 to Dolle et al (C on form PTO-892).

The '791 and '981 patents have been discussed supra.

The combined disclosures do not specifically recite protease inhibitors in a medicament for multiple sclerosis.

The '800 patent teaches a pharmaceutical composition comprising a protease inhibitor for the treatment of IL-1 $\beta$  mediated disease states (column 7, lines 39-56 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '800 patent with the combined disclosures of the '791 and '981 patents. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '800 patent that multiple sclerosis is an IL-1 $\beta$  mediated disease state which can be treated with medicaments comprising a protease inhibitor.

8. Claims 43, 65 and 66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-11 of U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892) and U.S. Patent No. 4,129,666 to Wizerkaniuk (D on form PTO-892).

The '791 and '981 patents have been discussed supra.

The combined disclosures do not specifically recite the use of a rotating pan for application of the enteric coating to the solid form of the pharmaceutical composition.

The '666 patent teaches the application of enteric coating medicinal pellets with an enteric coating using a rotating pan apparatus (entire patent).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '666 patent with the combined disclosures of the '791 and '981 patents. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '666 patent that methods of applying an enteric coating such as spraying requires the use of solvents which may be toxic, while the rotating pan method does not require such solvents (column 1, lines 24-56 in particular).

9. Claims 1, 3-43, 50-54 and 61-66 are directed to an invention not patentably distinct from claims 7-14 of commonly assigned U.S. Patent No. 6,214,791 to Arnon et al (on form PTO-1449 filed July 8,

Art Unit: 1644

2002 – courtesy copy filed May 5, 2003). Specifically, the instant claims are not distinct from the invention claimed in the '791 patent for the reasons set forth supra in the obviousness-type double patenting rejections.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,214,791, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



Art Unit: 1644

10. Claims 1, 3-43, 50-54 and 62, 63 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,214,791 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) or WO 98/30227 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003), either in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892).

The '791 patent has been discussed supra.

The '227 publication (and the '791 patent which corresponds thereto) teaches a pharmaceutical composition comprising as an active ingredient a therapeutically effective amount of Copolymer 1(glatimer acetate). The '227 publication teaches a method of treating multiple sclerosis by oral administration of copolymer-1 through ingestion, and that when copolymer-1 is introduced orally it may be in solid form, and it may be mixed with pharmaceutically acceptable carrier. The '227 publication teaches that the use of enteric coatings is well known in the art, including methacrylic acid copolymer (Eudragit L; page 5, lines 20-31 in particular)[Instant claims 18, 20, 29-31]. The '227 publication teaches the administration of the composition orally, nasally or bronchially in liquid or solid form with a range of copolymer-1 from 0.1 to 1000 mg (page 4, line 9 to page 5, line 25) [claims 23-28, 32, 37-42, 50-54, 62-63].

The '791 patent and the '227 publication does not specifically teach that said carrier is microcrystalline cellulose or the incorporation of lubricants.

Microcrystalline cellulose is well known in the art as a stable and physiologically inert expipient. The '981 patent teaches that microcrystalline cellulose is a non-effervescent wicking or disintegration agent for solid compositions such as tablets (column 13, lines 47-59 in particular) and that tablets can be made in unit dosage forms adapted for oral administration (column 4, lines 30-35). The '981 patent teaches that the percentage of active ingredient, and therefore of the carrier in proportion to that active ingredient, in a solid pharmaceutical preparation may be selected according to known principals of pharmacy (column 5, lines 12-14 in particular). The '981 patent teaches that the active ingredient used can vary greatly and is generally provided in an amount between greater than zero and 80% (column 5, lines 34-56 in particular). The '981 patent teaches that a typical range for a disintegrant such as microcrystalline cellulose is conventionally as high as 20% but can be increased for rapidly disintegrating dosage forms (column 13, lines 60-67 in particular)[Instant claims 1, 3-8]. The '981 patent also teaches modified starches as a disintegration agent (column 13, lines 47-59 in particular)[Claims 8-14]. The '981 patent further teaches lubricants, including magnesium stearate (column 10, lines 13-51 in particular)[claims 15-17]. Claims 34-35 are included because the use of preservatives in pharmaceutical formulations is well known to enhance the longevity of the formulation in storage.

Art Unit: 1644

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to manufacture a composition comprising copolymer-1 as taught by the '791 patent or the '227 publication using the well-known microcrystalline cellulose as an excipient and magnesium stearate as a lubricant, optimizing the proportions of active ingredient as taught by the '981 patent. One would have been motivated to combine these teachings because thus formed composition can be used as a medicament.

11. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,214,791 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) or WO 98/30227 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003), either in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892) as applied to claim 1 above, and further in view of U.S. Patent No. 6,162,800 to Dolle et al (C on form PTO-892).

The '791 and '981 patents and the '227 publication have been discussed supra.

The combined disclosures do not specifically recite protease inhibitors in a medicament for multiple sclerosis.

The '800 patent teaches a pharmaceutical composition comprising a protease inhibitor for the treatment of IL-1 $\beta$  mediated disease states (column 7, lines 39-56 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '800 patent with the teachings of the '791 patent or the '227 publication combined with the teachings of the '981 patent. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '800 patent that multiple sclerosis is an IL-1 $\beta$  mediated disease state which can be treated with medicaments comprising a protease inhibitor.

12. Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,214,791 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) or WO 98/30227 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003), either in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892) as applied to claims 1 and 43 above, and further in view of U.S. Patent No. 4,129,666 to Wizerkaniuk (D on form PTO-892).

The '791 and '981 patents and the '227 publication have been discussed supra.

The combined disclosures do not specifically recite the use of a rotating pan for application of the enteric coating to the solid form of the pharmaceutical composition.

Art Unit: 1644

The '666 patent teaches the application of enteric coating medicinal pellets with an enteric coating using a rotating pan apparatus (entire patent).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '666 patent with the teachings of the '791 patent or the '227 publication combined with the teachings of the '981 patent. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '666 patent that methods of applying an enteric coating such as spraying requires the use of solvents which may be toxic, while the rotating pan method does not require such solvents (column 1, lines 24-56 in particular).

13. Claims 21, 22 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,214,791 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003) or WO 98/30227 (on form PTO-1449 filed July 8, 2002 – courtesy copy filed May 5, 2003), either in view of U.S. Patent No. 6,024,981 to Khankari et al (A on form PTO-892) as applied to claims 1, 20 and 43 above, and further in view of U.S. Patent No. 5,965,600 to Sato et al (B on form PTO-892).

The '791 and '981 patents and the '227 publication have been discussed supra.

The combined disclosures do not specifically recite film coating of the solid form in combination with the enteric coating.

The '600 patent teaches a medicament in tablet form comprising both an enteric coating and a film coating, which could be polyvinyl alcohol (column 4, lines 39-62 in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '600 patent with the teachings of the '791 patent or the '227 publication combined with the teachings of the '981 patent. One would have been motivated to combine the references with a reasonable expectation of success by the teaching of the '600 patent that multiple coatings of a tablet including both enteric and film coatings is "customary" in the art.

#### *Conclusion*

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Art Unit: 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
July 14, 2003



CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600